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(21) International Application Number: PCT/US99/17179 (22) International Filing Date: 29 July 1999 (29.07.99) (30) Priority Data: 60/094,687 30 July 1998 (30.07.98) US (71) Applicant (for all designated States except US): NOVOPHARM BIOTECH, INC. [CA/CA]; 30 Novopharm Court, Toronto, Ontario M1B 2K9 (CA). (72) Inventors; and (73) Inventors/Applicants (for US only): KADIMA, Tenshuk, A. [CA/CA]; 7 Woodington Bay, Winnipeg, Manitoba R3P 1M6 (CA). KAPLAN, Howard, A. [CA/CA]; 18 Hillhouse Road, Winnipeg, Manitoba R2V 2V9 (CA). TUTTLE, Robert, C. [US/CA]; 782 Allegheny Drive, Winnipeg, Manitoba R3T 5L2 (CA). (74) Agents: WU, Frank et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).	(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: PHARMACEUTICALLY ACCEPTABLE COMPOSITION COMPRISING AN AQUEOUS SOLUTION OF PACLITAXEL AND ALBUMIN		
(57) Abstract An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10 % organic solvent and has a pH of about 3.0 to about 4.8, is described. The serum albumin can be fatted or defatted, and the composition can optionally be lyophilized or optionally lyophilized and reconstituted. At least 70 % of the paclitaxel is bound to serum albumin, the ratio of paclitaxel to albumin is at least about 1:5, and the concentration of paclitaxel is at least about 25 µg/ml. Methods of making and using this composition are also provided.		